

July 13, 2004

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Division of Documents Management
(HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

RE: Docket No. 200N-0278: Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 and "Joint FDA-CBP Plan for Increasing Integration and Assessing the Coordination of Prior Notice Timeframes" (69 Fed. Reg. 19763 and 19765 (April 14, 2004) and 69 Fed. Reg. 28060 (May 18, 2004))

Dear Sir/Madam:

The undersigned are a coalition of trade associations representing all tiers of the beverage alcohol industry. Members of our associations are involved in the production, importation, distribution/wholesaling, and retailing of beverage alcohol products that are sold throughout the United States.

On behalf of the beverage alcohol industry, we appreciate the opportunity to comment upon the Food and Drug Administration's (FDA) prior notice interim final rule implementing the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act) and the proposed "Joint FDA-CBP Plan for Increasing Integration and Assessing the Coordination of Prior Notice Timeframes" (Joint FDA-CBP Plan). Our coalition includes all segments of our industry both here in the United States and around the world and the suggestions set forth below will enable FDA to best achieve the objectives of the prior notice requirements without burdening the regulated community with overlapping and duplicative rules.

At the outset, we want to once again commend the FDA for its outreach efforts and guidance documents to educate all affected parties about the requirements of FDA's rules. The beverage alcohol industry has been very aggressive in terms of ensuring that all of our trading partners are fully acquainted with the provisions of the Bioterrorism Act and its requirements. FDA officials, particularly Deputy Director Carson, have been of extraordinary assistance in that regard and we particularly are indebted to the time and guidance imparted to us by Mr. Carson.

We supplement our December 24, 2003 prior notice comments with the following specific suggestions:

1. **FDA-Customs and Border Protection (CBP) integration of systems and timeframes**

We support the objective of the Joint FDA-CBP Plan to achieve a uniform, integrated system and to coordinate the timeframes for the required prior notice of imports for air, highway and rail modes with CBP's advance electronic information rule. Such an approach will allow all

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affected parties to devote increased resources to enhance security. Coordination between the two agencies will eliminate the duplication of efforts and reduce confusion while at the same time further the goal of a safe and secure food supply.

To that end, we urge FDA to conform the prior notice deadlines for the air, highway and rail mode timeframes to those applicable to these respective modes under Customs' advance electronic information requirements. Thus, prior notice for imports by air would be required no later than four hours prior to arrival in the United States (or "wheels up" for flights from North America, Central America, South America (north of the equator), the Caribbean, and Bermuda). Prior notice for imports by highway would be required no later than one hour (or currently 30 minutes if the filer is a participant in CBP's voluntary Free and Secure Trade (FAST) program) prior to arrival in the United States. Prior notice for imports by rail would be required no later than two hours prior to arrival in the United States.

In addition, food products subject to FDA's prior notice requirements should be eligible for full expedited processing and information transmission benefits that are available to importers via CBP's filing and clearance systems. The compressed, shorter CBP timeframes for imported products should be available to all filers of FDA's prior notices and our coalition's products underscore this point. Beverage alcohol already is one of the most highly regulated products with a comprehensive regulatory scheme that ensures its safe transport. Many of the regulations governing the transport of beverage alcohol pertain to potential tax liability and, as an ancillary consequence, require great regard and supervision associated with transport. Expedited prior notice processing and other flexible alternatives for imported beverage alcohol products will not compromise the objectives of the Bioterrorism Act and will serve other Government interests and enhance the flow of commerce.

Finally, to fully achieve the FDA-CBP goal of coordinating timeframes, FDA should adopt the "point of entry," rather than the "point of arrival" in the U.S. to measure the timeliness of the prior notice filing. CBP's "point of entry" is well known to importers and its use for purposes of the Bioterrorism Act not only will alleviate unnecessary confusion, but also will facilitate the stream of U.S. commerce without compromising food safety.

FDA developed the concept of "port of arrival" in the prior notice interim final rule because it lacked sufficient numbers of FDA personnel to cover every port of entry. With the growing partnership between FDA and CBP, FDA's concern regarding limited personnel should no longer be an issue now that FDA and Customs collectively are using their respective enforcement officials for this joint endeavor.

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2. The definition of "article of food"

The current rule requiring a separate prior notice for each size of the same brand produced by the same manufacturer imposes a substantial and unnecessary burden upon the resources of both the Government and industry. For example, under the current regulatory framework, an importer making a single shipment of a manufacturer's three brands of a food product in two different container sizes would file six prior notices. FDA can reduce the paperwork burdens of the current scheme substantially for both Government and industry, without impacting adversely upon the ability of FDA to trace imports, by allowing a single prior notice for different container sizes and different brands of the same manufacturer. Thus, the importer in the above-referenced example would be able to file a single prior notice describing the three brands in two different container sizes.

3. Registration number of quality control and other samples

We urge FDA to adopt the recommendation of other food industry members, such as the Grocery Manufacturers of America (GMA), to eliminate the requirement to list in the prior notice the facility registration number for product samples not intended for public consumption or for retail sale. This action will resolve the unaddressed issue of filing prior notices where registration numbers simply are not accessible, available or do not exist. Often a sample imported for analysis is a competitor's product and thus the registration number is not available. Further, some samples are provided by companies not conducting business in the U.S. and therefore are not required to register; consequently, no registration number exists. Developing a category for which a registration number is not required in the prior notice, such as for samples not intended to be consumed by the general public or for retail sale, will reduce the burden imposed upon FDA's limited resources and will in no way compromise the security and safety of the food supply.

4. Timely amendment of clerical errors

Under the interim final rule, with few exceptions, any change to information contained in the prior notice submission is prohibited once FDA has confirmed the submission for review. We urge FDA to expand the scope of exceptions to permit correction of information resulting from typographical or other clerical errors provided these corrections are executed prior to the applicable deadline for the prior notice. Allowing for such an exception would reduce the burden upon both the regulated and the regulating communities without jeopardizing the security and safety of the food supply.

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5. Notifying the filer of the prior notice of a deficiency in the prior notice

FDA has stated that, if food is refused admission due to an inadequate prior notice, FDA or CBP will notify the carrier of the food shipment of the refusal when the food is presented for CBP processing. We urge FDA to notify directly the person who filed the prior notice. The filer of the prior notice – who is in most cases the importer, supplier, owner of the merchandise, or a representative of one of these entities – should be notified directly, without any intermediate communication, so that the filer may promptly take corrective action and mitigate any possible adverse regulatory and commercial consequences.

Conclusion

Thank you for the opportunity to present our views concerning the operation of FDA's prior notice interim final rule and to offer our suggestions to further streamline and enhance the efficient and effective implementation of the prior notice requirements by Government and industry.

Once again, we commend FDA, particularly Deputy Director Carson, for his ever willingness to respond to our questions and provide guidance. We also commend FDA and CBP for their collaboration in streamlining the Bioterrorism Act's requirements and urge that this partnership continue in order to achieve even greater efficiencies.

If you have any questions regarding our comments, please do not hesitate to contact us.

Sincerely,

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